



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL - 2 1999

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The Honorable Richard Shelby
United States Senate
Washington, D.C. 20510-0103

Dear Senator Shelby:

Thank you for your letter of May 26, 1999 on behalf of Mr. Macon L. Bynum of Huntsville, Alabama, concerning actions by the Food and Drug Administration (FDA or the Agency) in regard to labeling of foods treated with ionizing radiation.

The 1997 FDA Modernization Act (PL 105-115) states that "[n]o provision . . . shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients . . ." FDA published a final rule implementing this provision of the law in the Federal Register of August 17, 1998. A copy of this regulation, along with the pre-existing labeling requirements for food treated with ionizing radiation (21 CFR 179), are enclosed for your information.

In addition, the Statement of Managers accompanying the FDA Modernization Act directed FDA to publish for public comment further proposed changes to the Agency's current labeling regulations. The managers stated their intention that any required labeling be of a type and character such that it would not be perceived to be a warning or give rise to inappropriate consumer anxiety. On February 17, 1999, FDA published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register soliciting public comment on whether additional revisions to the current irradiation labeling requirements are needed and, if so, what form such revisions might take. The deadline for comments in response to the ANPR has been extended to July 19, 1999.

98N 1038

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We have forwarded Mr. Bynum's correspondence to the Docket for inclusion in the record. FDA's final approach to labeling of irradiated foods will take into account all of the data and information received.

Because your constituent may be concerned about irradiation labeling for meat and poultry, you may also wish to contact the United States Department of Agriculture (USDA) for information. (USDA has primary regulatory authority over meat and poultry products, including the labeling of such products.)

We have also enclosed some general background on the issue of irradiation. We trust this responds to your concerns.

Sincerely,


Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

Enclosures

cc: Dockets Management Branch
(98N-1038)

RICHARD SHELBY
ALABAMA

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May 26, 1999

The Acting Associate Commissioner
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Dear Sir or Madame:

Enclosed please find a copy of correspondence I received from Macon L. Bynum.

Please reply, **in duplicate**, to my aide, CASSONDRA COLLINS.

Sincerely,



Richard Shelby

RCS/cdc
Enclosure

No. 99- 3888

Macon L. (Rusty) Bynum
4318 Shelby Ave. SE
Huntsville, AL 35801-1053
256-539-1689
Email: bsquared@traveller.com

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391635

May 13, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No 98N-1038, Irradiation-in the Production, Processing and Handling of Food

To whom it may concern:

I support the recommendation by the Center for Science in the Public Interest regarding labeling of irradiated foods:

"any foods, or any foods containing ingredients that have been treated by irradiation, should be labeled with a written statement on the principal display panel indicating such treatment. The statement should be easy to read and placed in close proximity to the name of the food and accompanied by the international symbol. If the food is unpackaged, this information should be clearly displayed on a poster in plain view and adjacent to where the product is displayed for sale."

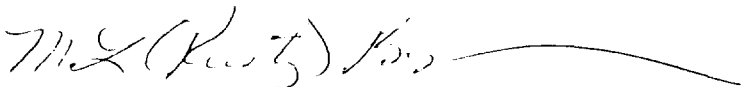
Like other labels, irradiation labels are required by FDA to be truthful and not misleading. I believe that the terms "treated with radiation" or "treated by irradiation" should be retained. Any phrase involving the word "pasteurization" is misleading because pasteurization is an entirely different process of rapid heating and cooling.

I recognize the radura as information regarding a material fact of food processing. The requirement for irradiation disclosure (both label and radura) should not expire at any time in the future. The material fact of processing remains. Even if some consumers become familiar with the radura, the market is constantly changing. In order to adequately inform all consumers, the symbol should be clearly understandable at the point of purchase for every one. If there is no label, consumers will be misled into believing the food has not been irradiated.

I urge you to place the comments received on the Internet so that the public can be informed about who is participating in this comment process.

After all, agriculture is everybody's business, and everybody has a right to know what they're eating.

Sincerely,



Macon L. (Rusty) Bynum

cc: Secretary Donna Shalala
Senator Richard C. Shelby
Senator Jeff Sessions
Representative Bud Cramer